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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,261	12/06/2000	Joel F. Habener	17633/1230	9060

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731,261

Applicant(s)

HABENER ET AL.

Examiner

Anne Marie S. Wehbe

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,21-23,42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,21-23,42 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment after-final received on 3/3/06 has been entered. Claims 1-18, 20, 24-41, and 44 are canceled. Claims 19, 21-23, and 42-43 are currently pending and under examination in the instant application. The finality of the previous office action has been **withdrawn** and prosecution in the instant application is reopened in view of new grounds of rejections presented below. An action on the merits follows. Those sections of Title 35, US code, not included in this action can be found in previous office actions.

The terminal disclaimer filed on 3/3/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application No. 09/963,875 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19, 21-23, and 42-43 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19, step (c), is confusing in that it is unclear whether non-migrated or migrated nestin positive cells are selected. It is suggested that the applicant amend claim 19, step (c), to recite, “and selecting said migrated nestin-positive cells from the culture”. Claims 21 and 42 depend on claim 19.

Claims 19 and 43 are confusing in that the preamble does not reflect the cells which are isolated using the method as written. The method as written results in nestin positive cells whereas the preamble recite “a stem cell”. It is suggested that the claims be amended in line 1 to recite a “nestin-positive stem cell” and that step (c) for claim 19 and step (e) for claim 43 be amended to recite “nestin-positive stem cell”. Claims 21 and 42 depend on claim 19.

Claim 22 is confusing in that the preamble indicates refers to an **isolated** nestin-positive pancreatic stem whereas the method step simply refers to a nestin-positive pancreatic stem cell. As such, the method steps do not correspond in scope to the claim preamble. It is suggested that claim 22, line 3 be amended to insert “isolated” before “nestin-positive pancreatic stem cell”. Claim 23 depends on claim 22.

Claim Rejections - 35 USC 102

The rejection of claims 24-29, and 44 under 35 U.S.C. 102(b) as being anticipated by WO 97/15310 (5/1/97), hereafter referred to as Peck et al., is withdrawn in view of applicant's cancellation of the claims.

Claims 22-23 are newly rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/15310 (5/1/97), hereafter referred to as Peck et al. The applicant claims a method of inducing the differentiation of an isolated nestin-positive pancreatic stem cell into a pancreatic progenitor cell comprising treating a nestin-positive pancreatic stem cell with an agent selected from a group which includes high glucose, EGF, and HGF/SF.

Peck et al. teaches isolated pancreatic stem cells, including isolated human pancreatic stem cells, and methods of inducing the pancreatic stem cells to differentiate into semi-mature and mature cell types such as insulin-producing beta cells, glucagon producing alpha cells, which are further capable of producing islet like aggregates comprising different mature cell types (Peck et al., pages 14-15, 22, 28-29, and page 45, claim 1). In particular, Peck et al. teaches that treating pancreatic stem cells with high glucose, or such factors as EGF or HGF/SF induces the differentiation of the pancreatic stem cells (Peck et al., page 15, lines 16-25).

Please note that while Peck et al. does teaches methods for identifying marker proteins specific to pancreatic stem cells versus more differentiated cell types, see pages 32-35, and also teaches isolating pancreatic stem cells based on specific marker proteins, see pages 35-36, Peck et al. does not specifically teach that nestin is a marker for pancreatic stem cells. However, since Peck et al. teaches pancreatic stem cells and further teaches that these cells have the same capacity to differentiate into more mature cell types as nestin positive pancreatic stem cells disclosed in the instant specification, nestin expression by pancreatic stem cells is considered an inherent property of the stem cells disclosed by Peck et al.. The applicant is reminded that , “When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent.” See MPEP 2112.01 or In re Best,

195 USPQ 430, 433 (CCPA 1997). The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPAI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989).

Therefore, by teaching all the limitations of the claims as written, Peck et al. anticipates the instant claims.

Double Patenting

The provisional rejection of claims 24-28 under 35 U.S.C. 101 as claiming the same invention as that of claims 39 and 43 of copending Application No. 09/963,875, hereafter referred to as the '875 application, is withdrawn in view of the cancellation of claims 24-28.

It is noted that applicants have filed a terminal disclaimer over Application No. 09/963,875. Since the rejection of record was a statutory double patenting rejection under 35 U.S.C. 101, a terminal disclaimer would **not** have overcome this rejection. However, since claims 24-28 were canceled, the rejection has been withdrawn.

The provisional rejection of claims 19, 21-23, 29, and 43-44 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39-43 of copending Application No. 09/963,875, hereafter referred to as the '875 application, is withdrawn in view of applicant's filing of a terminal disclaimer on 3/3/06.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

